



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3305-FN]

Medicare and Medicaid Programs; Continued Approval of the American Association for Accreditation of Ambulatory Surgery Facilities' Accreditation Program for Organizations that Provide Outpatient Physical Therapy and Speech Language Pathology Services

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Association for Accreditation of Ambulatory Surgery Facilities for continued recognition as a national accrediting organization for organizations that provide outpatient physical therapy and speech language pathology (OPT) services that wish to participate in the Medicare or Medicaid programs. An OPT that participates in Medicaid must also meet the Medicare Conditions of Participation.

DATES: This final notice is effective April 22, 2015 through April 22, 2019.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as an outpatient physical therapy and speech language pathology (OPT) provided certain requirements are met. Section 1861(p)(4) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as an OPT. Regulations concerning Medicare

provider agreements are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of providers and certain types of suppliers are at 42 CFR part 488. The regulations at 42 CFR part 485, subpart H specify the specific conditions that a provider must meet to participate in the Medicare program as an OPT.

Generally, to enter into a Medicare provider agreement, a facility must first be certified by a State Survey Agency as complying with the conditions or requirements set forth in part 485, subpart H of our Medicare regulations. Thereafter, the OPT is subject to periodic surveys by a State Survey Agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by state agencies. Accreditation by a national Medicare accreditation program approved by the Center for Medicare & Medicaid Services (CMS) may substitute for both initial and ongoing state agency review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accreditation organization meets or exceeds all applicable Medicare conditions or requirements, we may “deem” the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A, implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide CMS with reasonable assurance that its accredited provider entities meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at §§ 488.4 and 488.8(d)(3). The regulations at § 488.8(d)(3) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by the CMS. The American Association for Accreditation of Ambulatory Surgery Facilities

(AAAASF's) current term of approval as a Medicare accreditation program for OPTs expires April 22, 2015.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days of receipt of an organization's complete application, we must publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provide at least a 30-day public comment period. At the end of the 210-day period, we must publish a notice announcing our approval or denial of an application.

III. Provisions of the Proposed Notice

On November 21, 2014, we published a proposed notice in the **Federal Register** (79 FR 69481) entitled "Application from the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Approval of its Accreditation Program for Organizations that Provide Outpatient Physical Therapy and Speech Language Pathology Services" announcing AAAASF's request for continued approval of its Medicare OPT accreditation program. In that notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.4 and §488.8, we conducted a review of AAAASF's Medicare OPT accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AAAASF's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its OPT surveyors; (4) ability to investigate and respond appropriately to complaints against accredited OPTs; and (5) survey review and decision-making

process for accreditation.

- The comparison of AAAASF's Medicare accreditation program standards to our current Medicare OPT Conditions of Participation (CoPs).

- A documentation review of AAAASF's survey process to:

- ++ Determine the composition of the survey team, surveyor qualifications, and AAAASF's ability to provide continuing surveyor training.

- ++ Compare AAAASF's processes to those we require of State Survey Agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited OPTs.

- ++ Evaluate AAAASF's procedures for monitoring OPTs it has found to be out of compliance with AAAASF's program requirements. (This pertains only to monitoring procedures when AAAASF identifies non-compliance. If noncompliance is identified by a State Survey Agency through a validation survey, the State Survey Agency monitors corrections as specified at §488.7(d).

- ++ Assess AAAASF's ability to report deficiencies to the surveyed OPT and respond to the OPT's plan of correction in a timely manner.

- ++ Establish AAAASF's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of AAAASF's staff and other resources.

- ++ Confirm AAAASF's ability to provide adequate funding for performing required surveys.

- ++ Confirm AAAASF's policies with respect to surveys being unannounced.

- ++ Obtain AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require,

including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the November 21, 2014 proposed notice also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare CoPs for OPTs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared AAAASF's OPT accreditation requirements and survey process with the Medicare CoPs of part 485, subpart H and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of AAAASF's OPT application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, AAAASF has completed revising its standards and certification processes in order to meet the requirements at:

- Section 488.4(a)(3)(ii), to ensure surveyors are provided the necessary tools to evaluate compliance with the Medicare conditions.

- Section 488.4(a)(3)(iii), to ensure the accreditation review process and accreditation decision making process meets the Medicare requirements, the following was modified:

- ++ Policy related to how AAAASF verifies an organization without a CMS certification number (CCN) seeking an initial survey has completed the Medicare enrollment application prior to receiving an accreditation survey;

- ++ Policy for establishing an effective date for renewal surveys;

- ++ Policy for withdrawals and terminations; and

- ++ Guidance and instructions on how plans of correction are handled when they are not

adequate.

- Section 488.4(a)(6), to address the requirement where complaints that do not rise to the level of requiring an onsite investigation are tracked and trended for potential focus areas during the next onsite survey.
- Section 488.9, to address the number of medical records reviews that must be completed onsite.
- Section 488.26(b), to ensure survey reports contain the appropriate level of deficiency (that is, standard versus condition).
- Section 488.28(a), to ensure plans of correction correct the cited deficiencies, include thresholds of compliance and are sent timely.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AAAASF as a national accreditation organization for OPTs that request participation in the Medicare program, effective April 22, 2015 through April 22, 2019.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Dated: April 13, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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